# Cancer risk estimation study program in patients treated with insulin in France (GROC)

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# Administrative details

**Study description** 

EU PAS number	
EUPAS3105	
Study ID	
40861	
DARWIN EU® study	
No	
Study countries	
France	

A suspected higher risk of cancer in insulin glargine (IG) than in human insulin (HI) users was investigated in the EGB database, a permanent representative sample of the French national healthcare insurance database, over the period from January 1st, 2003 to June 30th, 2010. Methods: Cox proportional hazards time-dependent models stratified on the propensity score quartiles for use of IG vs. HI, and adjusted on insulin, biguanide and sulfonylurea possession rates were used to assess the risk of cancer or death in incident or all exclusive or predominant (≥ 80% use time) IG users compared to equivalent HI users. Results: Only type 2 diabetic patients were studied. Exposures varied from 2273 and 614 patient-years for incident exclusive IG or HI users respectively, to 3125 and 2341 patient-years for all predominant IG or HI users. All-type cancer hazard ratios (HR) with IG vs. HI ranged from 0.59 (95% confidence interval (CI) 0.28, 1.25) in incident exclusive users to 0.58 (95%CI 0.34, 1.01) in all predominant users. Cancer risk increased with exposure to insulin or sulfonylureas in these patients. Adjusted HR for death or cancer associated with IG compared to HI ranged from 0.58 (95%CI 0.32, 1.06) to 0.56 (95%CI 0.36, 0.87). Conclusion: There was no excess risk of cancer in type 2 diabetic patients on insulin glargine alone compared to human insulin alone. The overall risk of death or cancer in patients on glargine was about half that of patients on HI, thereby excluding bias from competing risk of death.

#### **Study status**

Finalised

## Research institutions and networks

## Institutions

Bordeaux PharmacoEpi, University of Bordeaux



## Contact details

#### **Study institution contact**

Patrick Blin plateforme.bpe@u-bordeaux.fr

Study contact

plateforme.bpe@u-bordeaux.fr

## **Primary lead investigator**

Patrick Blin

**Primary lead investigator** 

# Study timelines

Date when funding contract was signed

Actual: 18/10/2010

**Study start date** 

Actual: 07/12/2010

#### Data analysis start date

Actual: 14/02/2011

#### Date of final study report

Actual: 20/09/2011

# Sources of funding

- Other
- Pharmaceutical company and other private sector

## More details on funding

Sanofi, University of Bordeaux

# Study protocol

PAS Lantus 10032011.pdf (610.57 KB)

Synopsis LANTUS 06122010.pdf (777.39 KB)

# Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

# Methodological aspects

# Study type

Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

#### Study type:

Non-interventional study

#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

#### **Data collection methods:**

Secondary use of data

#### Main study objective:

study the posssible relationship between exposure to insulin glargine and the diagnosis of cancer

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

#### **Anatomical Therapeutic Chemical (ATC) code**

(A10A) INSULINS AND ANALOGUES

**INSULINS AND ANALOGUES** 

#### Medical condition to be studied

# Population studied

#### Short description of the study population

The study population was selected from the data available in the EGB on October 1, 2010.

The study population allowing the analysis of exposure to insulins is composed of of all EGB patients who have made at least one reimbursement request insulin between January 1, 2003 and December 31, 2009 to the National Health Insurance Fund for Salaried Workers (CNAM-TS) in Metropolitan France.

The patients included in the analysis are the patients in the study population:

- aged 18 and over;
- without ALD cancer before the first delivery of insulin;
- with at least 2 insulin deliveries during follow-up until June 30 2010;
- whose 1st issue did not take place in the same month as the death;
- without an isolated health care consumption "hole" during their exposure to insulin (patients leaving then re-entering the EGB because having changed regime, migrant, etc., i.e. at least one year without any reimbursement of care.

#### Age groups

- Adults (18 to < 46 years)</li>
- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)</li>
- Adults (75 to < 85 years)
- Adults (85 years and over)

#### Special population of interest

Other

#### Special population of interest, other

Type 2 diabetes mellitus patients

#### **Estimated number of subjects**

5000

# Study design details

#### **Outcomes**

registration for a diagnosis of cancer in diabetic patients using insulin, relationship with duration and intensity of exposure (medication possession rates) to insulin, sulfonylureas and metformin.incidence rates for individual cancer types.

#### Data analysis plan

Cox time-dependent risk ratio and survival analysis of cancer adjusted for propensity score for exposure to human insulin vs glargine, in various user cohorts: incident exclusive users, all exclusive users, incident predominant users, all predominant users.

## **Documents**

#### **Study results**

LANTUS-Cohortes-Synthèse résultats-01032011.pdf (1.21 MB)

## Study publications

Blin P, Lassalle R, Dureau-Pournin C, Ambrosino B, Bernard MA, Abouelfath A, Gi...

## Data management

## **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

### Data sources

#### **Data sources (types)**

Administrative healthcare records (e.g., claims)

## Use of a Common Data Model (CDM)

#### **CDM** mapping

No

# Data quality specifications

#### **Check conformance**

Unknown

#### **Check completeness**

Unknown

#### **Check stability**

Unknown

#### **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

No